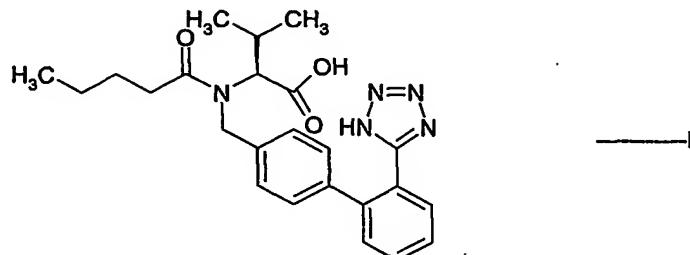


We claim:

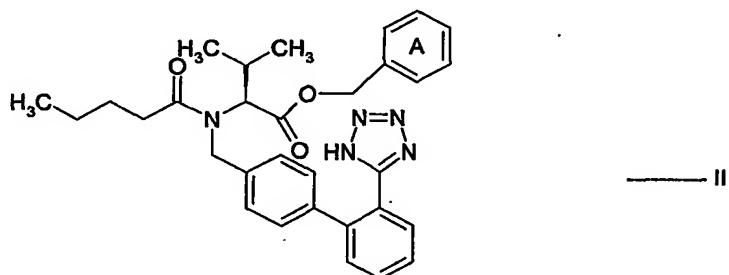
- 1) A process for the preparation of valsartan of formula I:



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which comprises the steps of:

- a) hydrolyzing the compound of the general formula II:



- wherein ring A is substituted or unsubstituted phenyl group,
- 10 with an excess alkali metal hydroxide;
- b) washing the aqueous layer containing reaction products of step (a) with an organic solvent;
- c) acidifying the aqueous layer using an acid; and
- d) isolating valsartan of formula I from the reaction mixture of step (c).
- 15 2) A process according to claim 1, wherein the ring A is phenyl.
- 3) A process according to claim 1, wherein the ring A is alkyl, halo, hydroxyl or nitro substituted phenyl.
- 4) A process according to claim 3, wherein the ring A is m-nitro phenyl or m-fluoro phenyl.
- 20 5) A process according to claim 1, wherein the alkali metal hydroxide is sodium hydroxide or potassium hydroxide.

- 6) A process according to claim 1, wherein the alkali metal hydroxide is sodium hydroxide.
- 7) A process according to claim 1, wherein the alkali metal hydroxide is used in an amount more than one molar equivalent relative to the compound of the formula II.
- 5 8) A process according to claim 7, wherein the alkali metal hydroxide is about 2 to 20 molar equivalent relative to the compound of the formula II.
- 9) A process according to claim 8, wherein the alkali metal hydroxide is about 3 to 8 molar equivalent relative to the compound of the formula II.
- 10 10) A process according to claim 1, wherein the hydrolysis is conducted in a mixed solution composed of water and a hydrophilic organic solvent.
- 11) A process according to claim 10, wherein the hydrophilic organic solvent is selected from methanol, ethanol, propanol, isopropanol and tert-butanol.
- 12) A process according to claim 1, wherein the organic solvent is selected from 15 benzene, toluene, xylene, n-hexane, n-heptane, cyclohexane, petroleum ether, diethyl ether, diisopropyl ether, tert-butyl methyl ether and a mixture thereof.
- 13) A process according to claim 12, wherein the organic solvent is selected from n-heptane, cyclohexane, n-hexane, petroleum ether and diisopropyl ether.
- 20 14) A process according to claim 13, wherein the organic solvent is n-heptane.
- 15) A process according to claim 13, wherein the organic solvent is diisopropyl ether.
- 16) A process according to claim 1, wherein the aqueous layer is acidified in 25 step (c) to below about pH 7.0.
- 17) A process according to claim 16, wherein the aqueous layer is acidified to about pH 4.0 to 1.0.
- 18) A process according to claim 17, wherein the aqueous layer is acidified to about pH 3.0 to 1.0.
- 30 19) A process according to claim 1, wherein the acid used in step (c) is hydrochloric acid or sulfuric acid.
- 20) A process according to claim 19, wherein the acid is hydrochloric acid.

- 21) A process according to claim 1, wherein the valsartan is isolated in step (d) by extracting into an organic solvent followed by removing the solvent or precipitating valsartan.
- 22) A process according to claim 21, wherein the organic solvent is selected
5 from methylene dichloride, chloroform, carbon tetrachloride, ethylene dichloride, ethyl acetate, methyl acetate, isopropyl acetate, tert-butyl acetate, ethyl formate, methyl formate and a mixture thereof.
- 23) A process according to claim 22, wherein the organic solvent is selected from methylene dichloride, chloroform and ethyl acetate.
- 10 24) A process according to claim 23, wherein the organic solvent is methylene dichloride and ethyl acetate.
- 25) A process according to claim 23, wherein the organic solvent is ethyl acetate.